

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Pellet and Sanchez-Martinez

Patent No. 6,126,944

Issued: October 3, 2000

Application No. 08/480,850

Filed: June 7, 1995

Confirmation No. 9684

For: BACULOVIRUS EXPRESSION VECTORS
AND RECOMBINANT ANTIGENS FOR
DETECTING TYPE-SPECIFIC
ANTIBODIES TO HERPES SIMPLEX
VIRUS

Examiner: Louise N. Leary

Art Unit: 1623

Attorney Reference No. 6395-87124-02

FILED VIA EFS

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COMMISSIONER FOR PATENTS

DECLARATION OF SUZANNE SEAVELLO SHOPE, J.D.

1. I, Suzanne Seavello Shope, J.D. work as the Technology Licensing and Marketing Scientist for the above referenced patent on behalf of the Assignee, which is The United States of America as Represented by the Secretary of the Department of Health and Human Services (hereinafter "the Government"). I am employed by the Government in the Technology Transfer Office (TTO) at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. I received my law degree (J.D.) in 1992 from the University of California, Hastings College of Law. I was registered as a patent attorney in 1994 and worked as a patent associate at several law firms, including Jones and Askew and Kilpatrick Stockton, from 1994-2003. I have worked in my current position at CDC since April 2003.

2. I was acting as the interim case manager for the above-referenced U.S. Patent No. 6,126,944 from June 2007 until about April 14, 2008. This was during a period of transition in our office when the prior case managers (Russ Metler and Sumita Chowdhury-Ghosh) had left the CDC TTO, new case managers (Francisco Candal and Valentin Fikovsky) were transitioning into those responsibilities, and hundreds of our case files were being transferred from our prior

counsel (Needle & Rosenberg) to our patent firms who had been awarded the new patent services contract.

3. As prescribed by federal procurement and contractual policies, the CDC is limited to using specific outside law firms that are retained under a Government patent services contract. On September 1, 2006, the CDC awarded a new seven-year patent services contract to two law firms. These two firms were Klarquist Sparkman LLP (hereinafter "Klarquist Sparkman") and Gifford, Krass, Sprinkle, Anderson & Citowski, P.C. (hereinafter "Gifford Krass"). As Needle & Rosenberg was no longer a designated contract law firm for the CDC, Needle & Rosenberg began transferring the active files, so that they could be handled by new contract attorneys, Klarquist Sparkman and Gifford Krass at the request of the CDC. It was the understanding of personnel in the CDC TTO in 2007 that files for patents and applications that were in active prosecution or required other action (such as payment of maintenance fees) were being transferred from Needle & Rosenberg directly to one of the two law firms awarded the new patent services contract. In addition, files for expired patents and abandoned patent applications would have been shipped from Needle & Rosenberg directly to the CDC for storage at the CDC Technology Transfer Office in Atlanta, Ga. These transfers occurred over an extended period of time as funds already obligated to Needle & Rosenberg under the prior contract were depleted. Thus, Needle & Rosenberg remained responsible for U.S. Patent No. 6,126,944 until the obligated funds for that matter were depleted.

4. On September 10, 2007 Francisco Candal received two e-mails from Alicia Sheffield of Needle & Rosenberg. I was copied on these e-mails, which contained lists of approximately 350 files still remaining at Needle & Rosenberg, and stated that approximately 27 of these were active patent files or families. The subject U.S. Patent No. 6,126,944 was listed in that e-mail, however I do not recall reading this email. At the time Mr. Candal was the lead contact on receiving these files and I was copied only as a reference, hence I would not have felt that I needed to read or respond to this e-mail.

5. On April 23, 2008, I was in the process of transferring responsibility for any patent cases I was handling to a new Patent Advisor, Valentin Fikovsky. For that purpose, I

requested a report from Needle & Rosenberg listing active cases that were still at Needle & Rosenberg. This report was received on April 24, 2008. Listed on this report were one active patent family (CDC Reference Number I-017-97-0) that had already been transferred to Klarquist Sparkman and another active patent family (I-006-97/0) that I discovered had been incorrectly sent directly to the CDC instead of a contract law firm. This report did not list the subject U.S. Patent No. 6,126,944 (CDC Reference Number E-021-91); if the subject patent were listed I would have also requested that this patent be transferred to our outside counsel. A copy of the April 24, 2008 email is attached as Exhibit 1. On April 24, 2008 I contacted Klarquist Sparkman and then had the two files for I-006-97/0 shipped from the CDC to Klarquist Sparkman.

6. On May 14, 2008, Mr. Valentin Fikovsky was the case manager for U.S. Patent No. 6,126,944 and another patent in this family, U.S. Patent No. 6,013,433. I was continuing to ensure prosecution-related correspondence for this patent family was sent to Mr. Fikovsky. At that time, I asked Mr. Fikovsky to help me locate a patent file related to the above-referenced patent, namely US Patent No. 6,013,433. Our file tracking system indicated that the patent file for U.S. Patent No. 6,013,433 (CDC reference number E-021-91/1) was still at Needle & Rosenberg, which was the CDC's former outside counsel for the above-referenced patent. I checked the electronic database, but there was no indication in our records that its maintenance fee was paid, nor was there any indication that the patent file was properly transferred to Gifford Krass or Klarquist Sparkman. On May 15, 2008, Mr. Fikovsky responded, stating that we did not receive notices that the maintenance fees were due for four patents, including U.S. Patent No. 6,126,944. Copies of these emails are provided in Exhibit 2.

7. On May 15, 2008, U.S. Patent No. 6,126,944 the deadline for paying the maintenance fee had not yet passed. All maintenance fees for the CDC are paid through outside law firms. Our maintenance fee payment system relied on our outside firms to provide reminders that such fees were due, and we are not aware of any situation in which maintenance fee instructions were overlooked using that system. However since the file for U.S. Patent No. 6,126,944 had been diverted from that well-functioning system during a time when hundreds of

files were being transferred from our prior counsel, the fee was not tracked and paid by the October 3, 2008 deadline.

8. On December 4, 2008, I was copied on an email from Francisco Candal, who is a Patent Advisor at the CDC, forwarding a Notice of Expiration ("Notice") for U.S. Patent No. 6,126,944. The other recipients of the e-mail were our Director, Andrew Watkins, patent advisor Valentin Fikovsky and licensing associate Donald Prather. The procedure at the CDC for docketing patent correspondence is that when correspondence arrives, it is first date-stamped by Sharon Shropshire and then forwarded by her to our administrative staff, Veronica Brown who calendared any due dates. After patent correspondence is calendared in the electronic database that correspondence is sent to a Patent Advisor. Since CDC TTO does not internally prosecute patent applications or pay maintenance fees, the normal procedure is that the Patent Advisor would be contacted by our outside patent counsel for any action required in response to any patent correspondence. As I was not working as the Patent Advisor for this matter, no action was required on my part.

9. On April 13, 2011, a search in PAIR was performed, to determine the patent term of U.S. Patent No. 6,126,944 in order to determine how long the CDC would continue to collect royalties on the licenses for this patent. At that time, it was confirmed that the second maintenance fee was never paid. On April 13, 2011 the CDC database (Inteum) still indicated that U.S. Patent No. 6,126,944 was issued and in good standing. There was no notation in our internal database that this patent had been abandoned. Since that time I and others at the CDC have worked diligently with Klarquist Sparkman to reconstruct the unusual events that resulted in nonpayment of the second maintenance fee, and to prepare this Declaration documenting those events.

10. The CDC has had systems and procedures in place to manage patent prosecution and the payment of maintenance fees since its Technology Transfer Office (TTO) was established in 1986. These systems and procedures, which relied on the CDC's outside patent firms, have operated successfully for 25 years. Thus I believe non-payment of the maintenance fees is an unusual exception to the otherwise well-functioning systems in place at CDC TTO, and these unusual circumstances were attributable to the transfer of the large number of files to

our new firms as our new patent contracts began during a time of transition of personnel at CDC TTO, and the unappreciated diversion of this file outside that well-functioning system.

11. All statements made herein and of my own knowledge are true and all statements made on information are believed to be true; and further, these statements were made with the knowledge that willful false statements and like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements made may jeopardize the validity of the application or any patent issuing thereon.

7/19/11
Date

Suzanne Seavello Shope
Suzanne Seavello Shope

From: William Noonan, M.D.
Sent: Thursday, April 24, 2008 2:41 PM
To: 'Shope, Suzanne (CDC/OD/OCOSO)'; 'Gwen Spratt'
Cc: 'Candal, Francisco (Paco) (CDC/OD/OCOSO)'; 'Fikovsky, Valentin (CDC/OD/OCOSO)';
Veronica Brown; 'Watkins, Andrew (CDC/OD/OCOSO)'; Deborah Martin
Subject: RE: 3 missing files; rest being shipped today

Dear Suzanne,

We have searched for the missing files, and have no record of receiving them. We have not been able to find them in our office.

Sorry,
Bill

William D. Noonan, M.D.
Patent Attorney
Klarquist Sparkman, LLP
One World Trade Center
Suite 1600
Portland, Or 97204
Tel. 503-595-5300
Fax 503-595-5301

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-----Original Message-----

From: Shope, Suzanne (CDC/OD/OCOSO) [<mailto:awd8@cdc.gov>]
Sent: Thursday, April 24, 2008 12:31 PM
To: Gwen Spratt; William Noonan, M.D.
Cc: Candal, Francisco (Paco) (CDC/OD/OCOSO); Fikovsky, Valentin (CDC/OD/OCOSO); Veronica Brown; Watkins, Andrew (CDC/OD/OCOSO)
Subject: 3 missing files; rest being shipped today

Dear Gwen and Bill,

Of the physical files we thought should be in CDC's possession, I cannot find folders for two abandoned applications and one pending US case. Below I have listed the files we found and the files we're missing. If you would each ask your file clerks to see if any of the three missing files are in one of your offices, that would be a big help:

I-006-97 N&R reference 14114.0330

We have files for active cases BR, AU and the U2; we are shipping these to Bill today for delivery tomorrow.
Extra files we are shipping today are: the expired PCT folder, the

expired provisional application (U1), a "prior art" bucket, U2 PCT folder, and U2 reference bucket

I-017-97 N&R reference 14114.0343

We have abandoned or expired folders for BR, CA, EP, IN, U1 and the PCT and are shipping those today.

****MISSING****: We do not have abandoned AU and U2, nor do we have the pending U3. If I understand the N&R labeling system correctly, U1 is the provisional 60/076,565, U2 was the national stage 09/623,038 filed 11/27/2000, RCE filed 1/24/2005, which had an outstanding office action for which there were no funds to respond, and U3 is the continuation application 11/599,107 filed on 11/14/06 in order to keep the case alive.

Extra files we are shipping

I-030-04 N&R reference 14114.0380

Expired PCT and U1 (provisional) files

Bill is opening the CA national phase, Gwen will be sending the EP and US national phase files. For the time being, Gwen is keeping the AU national phase file.

Thanks, Suzanne

Suzanne Seavello Shope, J.D.
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Centers for Disease Control and Prevention
Technology Transfer Office
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Atlanta, GA 30341
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sshope@cdc.gov or awd8@cdc.gov

From: Gwen Spratt [<mailto:GSpratt@needlerosenberg.com>]
Sent: Wednesday, April 23, 2008 6:09 PM
To: Shope, Suzanne (CDC/OD/OCSO)
Subject: List of CDC cases in N&R Custody

Here it is.

There are a couple on the list that I'm fairly sure we already sent to Paco, since the other cases in the family were sent to him. I'll check on that and hopefully have an answer when we talk tomorrow.

Gwen

-----Original Message-----

From: Shope, Suzanne (CDC/OD/OCSO) [<mailto:awd8@cdc.gov>]
Sent: Wednesday, April 23, 2008 2:53 PM
To: Gwen Spratt
Subject: RE: Updated Ades et al. status report

Thanks, Gwen. Is it still possible to get a report of all active CDC files at N&R? We could use the report for two things: to help with our discussions tomorrow, and also to help get our new patent advisor up to speed. We are asking the other two law firms to also provide the same report. Sincerely, Suzanne

Suzanne Seavello Shope
770-488-8613

From: Gwen Spratt [<mailto:GSpratt@needlerosenberg.com>]
Sent: Wednesday, April 23, 2008 12:17 PM
To: Shope, Suzanne (CDC/OD/OCSO)
Cc: Lewis, Catherine (CDC/OD/OCSO); Robertson, Cynthia (CDC/OD/OCSO); Alicia C. Sheffield;
14114.0341AU1.atlanta@nr.needlerosenberg.com
Subject: Updated Ades et al. status report

Suzanne,

This report strikes your matter I-014-00 (N&R: 14114.0341 series). It appeared on the earlier report by mistake. It was transferred to Klarquist in March, but it was not inactivated in our docket pending reply to our transfer letter by Bill Noonan.

Regards,
Gwen

Gwendolyn D. Spratt, Esq.
Needle & Rosenberg, P.C.
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678-420-9300 receptionist
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Case List of Active Patent Matters

Docket No.	Client Ref#	Country	Relation Type	Status	Appl. No.	Appl. Date	Patent No.	Grant Date	Title
14114.0310U1	E-148-96/0	U.S.	CIP	GRANTED	08679084	7/12/1996	57603020	3/12/1998	METHODS AND COMPOSITIONS FOR AN ARTIFICIAL LUNG ORGAN CULTURE SYSTEM
14114.0330AU1	I-006-97/0	Australia	ORIGINAL	GRANTED	36588099	4/20/1999	766096	11/19/2003	RAPID AND SENSITIVE METHOD FOR DETECTING HISTOPLASMA CAPSULATUM
14114.0343U3	I-017-97/0	U.S.	CONT.	FILED	11/699407	11/14/2006			EPITOPES PEPTIDES IMMUNOGENIC AGAINST STREPTOCOCCUS PNEUMONIAE
14114.0369AU1	I-039-00/0	Australia	ORIGINAL	FILED	2002305845	5/20/2002			PEPTIDE VACCINES AGAINST GROUP A STREPTOCOCCI
14114.0369CA1	I-039-00/0	Canada	ORIGINAL	FILED	2447599	5/20/2002			PEPTIDE VACCINES AGAINST GROUP A STREPTOCOCCI
14114.0369EP1	I-039-00/0	EPC	ORIGINAL	FILED	2734477.9	5/20/2002			PEPTIDE VACCINES AGAINST GROUP A STREPTOCOCCI
14114.0369U2	I-039-00/0	U.S.	ORIGINAL	FILED	10/477955	5/20/2002			PEPTIDE VACCINES AGAINST GROUP A STREPTOCOCCI
14114.0374U2	I-034-02/0	U.S.	ORIGINAL	FILED	10/536219	12/1/2003			MEASUREMENT OF TOTAL REACTIVE ISOCYANATE GROUPS IN SAMPLES USING BIFUNCTIONAL NUCLEOPHILES SUCH AS 1,8-DIAMINONAPHTHALEN
14114.0380EP1	I-030-04	EPC	ORIGINAL	FILED	5782425.2	7/29/2005			FUNCTIONAL EPITOPES OF STREPTOCOCCUS PNEUMONIAE PPSAA ANTIGEN AND USES THEREOF
14114.0380U2	I-030-04	U.S.	ORIGINAL	FILED	11/692719	7/29/2005			FUNCTIONAL EPITOPES OF STREPTOCOCCUS PNEUMONIAE PPSAA ANTIGEN AND USES THEREOF
14114.0381AU2		Australia	DIVISION	GRANTED	2003204215	5/15/2003	2003204215	4/26/2007	RECOMBINANT LIPIDATED PsaA PROTEIN, METHODS OF PREPARATION AND USE
14114.0381BR1		Brazil	ORIGINAL	FILED	PI9809097-0	1/14/1999			RECOMBINANT LIPIDATED PsaA PROTEIN, METHODS OF PREPARATION AND USE

CDC - 14114
Case List of Active Patent Matters

Docket No.	Client Ref#	Country	Relation Type	Status	Appl. No.	Appl. Date	Patent No.	Grant Date	Title
14114.0381CA1		Canada	ORIGINAL	FILED	2319404	1/14/1999			RECOMBINANT LIPIDATED PsαA PROTEIN, METHODS OF PREPARATION AND USE
14114.0381EP1		EPC	ORIGINAL	FILED	99903011.7	1/14/1999			RECOMBINANT LIPIDATED PsαA PROTEIN, METHODS OF PREPARATION AND USE
14114.0381JP1		Japan	ORIGINAL	FILED	2000-530614	1/14/1999			RECOMBINANT LIPIDATED PsαA PROTEIN, METHODS OF PREPARATION AND USE
14114.0381MX1		Mexico	ORIGINAL	FILED	7261	1/14/1999			RECOMBINANT LIPIDATED PsαA PROTEIN, METHODS OF PREPARATION AND USE
14114.0381NZ2		New Zealand	DIVISION	GRANTED	525674	5/5/2003	525674	5/12/2005	RECOMBINANT LIPIDATED PsαA PROTEIN, METHODS OF PREPARATION AND USE
14114.0381U2		U.S.	ORIGINAL	FILED	09/600057	1/14/1999			RECOMBINANT LIPIDATED PsαA PROTEIN, METHODS OF PREPARATION AND USE

-----Original Message-----

From: Watkins, Andrew (CDC/OD/OCSO)

Sent: Thursday, May 15, 2008 1:06 PM

To: Shope, Suzanne (CDC/OD/OCSO); Fikovsky, Valentin (CDC/OD/OCSO); Candal, Francisco (Paco) (CDC/OD/OCSO)

Subject: Re: Your Reference No. E-021-91/1; N&R Reference No. 14114.0368U4

Are these all licensed? If not, should we evaluate the wisdom of paying an 8 year maintenance fee before the CCID division director does that for us? If we should abandon due to age and lack of interest or lack of need for future position, I would prefer that recommendation come first from TTO, with a request to the division director to help evaluate the current and future scientific status of the invention.

Andrew

----- Original Message -----

From: Shope, Suzanne (CDC/OD/OCSO)

To: Fikovsky, Valentin (CDC/OD/OCSO); Watkins, Andrew (CDC/OD/OCSO); Candal, Francisco (Paco) (CDC/OD/OCSO)

Sent: Thu May 15 12:14:11 2008

Subject: RE: Your Reference No. E-021-91/1; N&R Reference No. 14114.0368U4

We've never tried to pay by credit card. I wonder if we could use CCID's credit card to pay these fees?

Andrew and Paco, do you have any suggestions??

Suzanne

Suzanne Seavello Shope

770-488-8613

From: Fikovsky, Valentin (CDC/OD/OCSO)
Sent: Thursday, May 15, 2008 12:06 PM
To: Shope, Suzanne (CDC/OD/OCSO)
Subject: RE: Your Reference No. E-021-91/1; N&R Reference No. 14114.0368U4

There are four issued patent cases in which Needle did not send out reminders. This is one of them. Cases are:

I-010-98 Wang et al

Method for the Determination of Hexavalent Chromium Using Ultrasonication

and Strong Anion Exchange Solid Phase Extraction -

US 6,808,931, issued 10/26/2004

4th year fee was due 4/26/08

In grace period. We need to pay with surcharge by 10/28/08 otherwise the patent lapses

E-210-94 Zeng et al

Acoustical Method and System for Measuring Barrier Membrane Thickness Correspondent Area Distribution

Using Maximum Transmission or Maximum Reflection Coefficients

6,089,094 issued July 18, 2000

8th year fee was due Jan 18, 2008

With surcharge we need to pay with surcharge by 7/18/08 else it lapses

E-021-91 Pellett et al

Recombinant Baculoviruses Expressing HSV-type Specific Antigens, gG-1 and gG-2

6,126,944 issued Oct. 3, 2000

8th year fee was due 4/3/2008

We need to pay with surcharge by 10/3/08 else it lapses

I-012-96 Critchfield et al

Method and Compositions for Inhibition of Viral Replication

6,274,611 issued 8/14/2001

Fee is due 2/24/2009, no surcharge

Given we have no CPA can we pay using the credit card? Or do we need task orders (I can't do these, my computer has no capability).

What do you think?

V

From: Shope, Suzanne (CDC/OD/OCSSO)
Sent: Wednesday, May 14, 2008 7:03 PM
To: Fikovsky, Valentin (CDC/OD/OCSSO)
Subject: RE: Your Reference No. E-021-91/1; N&R Reference No. 14114.0368U4

More info: I found a note in Intelem stating "CDC ltr re: instruction to N&R to paying 3rd quarter maintenance, dated 04/24/2007", but I find no record of such a letter. We need to know if Needle paid the maintenance fee or whether we need to revive, Suzanne

Suzanne Seavello Shope
770-488-8613

From: Shope, Suzanne (CDC/OD/OCSSO)
Sent: Wednesday, May 14, 2008 6:58 PM
To: Fikovsky, Valentin (CDC/OD/OCSSO)
Subject: FW: Your Reference No. E-021-91/1; N&R Reference No. 14114.0368U4

Liz Williams
Maintenance Fees and Annuities Dept.

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